

**REMARKS**

Claims 1-9, 11-14, and 26-44 are pending in the application.

With this Response, claims 1, 9, and 26 are amended. No claims are canceled or added.

Claims 1-9, 11-14, and 26-44 remain pending for consideration.

Support for the amendments to claims 1, 9, and 26 can be found in the specification as originally filed, for example, at original claims 3 and 30, and elsewhere.

Reconsideration and allowance of the claims as pending are respectfully requested.

**The Cited References**

Cited against the pending claims are Sharkey et al. (U.S. Patent No. 5,540,701) and Kirsch et al. (U.S. Patent No. 6,461,367).

The Sharkey reference is directed to a “passive fixation anastomosis device” and a catheter to install the device. As shown at figure 11 of the Sharkey reference, the catheter includes two balloons that can be inflated to cause a proximal end and a distal end of the fixation device to be expanded to deployed positions. The catheter is subsequently removed, leaving the passive fixation anastomosis device in place.

The Kirsch reference includes very substantial differences regarding method and device features. The Kirsch reference describes devices including a “trocar” and “sheath” or a combined “dual approximator,” either of which includes “everting prongs” for securing urethra and bladder tissue using a clamp instead of sutures. In use, a device is inserted within a urethra and the “everting prongs” are extended to “contact and evert” tissue (col. 7, line 67 - col. 8, line 3). This allows bladder and urethra tissue to be brought together so a clip can be applied to the tissues to hold the bladder tissue and urethra together. The “everting prongs” and the device are then removed from the urethra leaving only the clips in place.

**Claim Rejection - 35 USC § 102**

Claims 1, 2, 9, 11-12, 14, 26-29, 35, 39, and 43 are rejected under 35 U.S.C. 102 as being anticipated by Sharkey et al. (U.S. Patent No. 5,540,701).

Independent claims 1, 9 and 26 have been amended to provide that the tissue approximating structure (claim 1), tissue approximating means (claim 9) and second

tissue approximating structure (claim 26) are “elongate.” This overcomes the rejection of independent claims 1, 9, and 26, and claims dependent thereon, over the Sharkey et al. reference, which does not identically teach elongate tissue approximating structure. The balloon structure of the Sharkey reference has the form of a surface of an expanding membrane. The balloon, in the form of an expanding surface, is not “elongate” and cannot be considered to be “elongate.”

**Claim Rejection - 35 USC § 103**

Claims 3-8, 13, 30-34, 36-38, 40-42, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al. (U.S. Patent No. 5,540,701) in view of Kirsch et al. (U.S. Patent No. 6,461,367).

The rejections are traversed at least because there would be no reason for one of skill to combine the references as proposed, to replace the balloon structure of the primary (Sharkey) reference with an “everting prong” structure of the secondary Kirsch reference. This combination would cause the primary reference to be unsuitable for its intended purpose, and, therefore, is not a valid basis for rejection.

**The Rejections are Traversed**

The Office Action provides that the Sharkey reference shows the claimed device “except for the tissue approximating structure or the second tissue approximating structure comprising of multiple distal tines and multiple proximal tines. . . .” (Office Action, p. 4). The Kirsch et al. reference is cited for teaching the missing features of Sharkey et al.:

*It would have been obvious to one of ordinary skill in the art at the time of invention to replace the (second) tissue approximating structure of Sharkey et al. with one that comprises multiple distal and proximal opposing tines at the distal end of a catheter body, as taught by Kirsch et al. in order to facilitate the approximation of tissue portions by anchoring the urethral stump and bladder neck with tines to ensure proper connection between the urethra and bladder (col. 1, lines 38-40, Kirsch et al.) as well as to selectively approximate tissue when desired.*

The rejection is traversed.

The Sharkey reference does not either specifically teach or otherwise suggest an elongate tissue approximating structure. To the contrary, the Sharkey reference exclusively teaches -- and as a functional matter, no less, requires -- a non-elongate balloon that cannot seemingly be replaced by an elongate structure.

**Functional requirements of the Sharkey balloon, which are not met by the Kirsch “everting prongs,” would not allow replacement of the Sharkey balloon with the Kirsch “everting prongs.”**

The above-captioned reasoning of the rejection does not withstand scrutiny because the Kirsch “everting prong” structure would not perform the function of the Sharkey balloon, as would be required for the rejection to be supported.

The Sharkey balloon functions by producing an expanding balloon surface area. The expanding surface area pressures a portion of a passive fixation device. Pressure of the expanding surface area against a helical structure of the passive fixation device causes the helical structure to expand. See figures 12 and 13 of Sharkey. The structure of the balloon must include an expanding surface area that can contact the helical structure of the device.

In a structurally and functionally distinct manner, the Kirsch “everting prong” structure functions to “evert” tissue for the purpose of connecting the everted tissue to other tissue using a clip. See figures 11A and 11B of the Kirsch reference. The Kirsch “everting prongs” have an extendable (not expandable) length-wise structure with tips at the ends of the length-wise (“prong”) structure that contact and “evert” tissue. Unlike the Kirsch balloon, the length-wise prong structures include minimal and non-expanding surface area. The Office action does not provide any assertion or technical support to conclude that length-wise, extendable prongs of Kirsch would function in a manner like the expanding surface area of the Sharkey balloon, especially in view of the coiled, helical structure of the Sharkey passive fixation device. If the everting prongs would not perform the required function of the Sharkey balloon, one of skill would not have had any reason or motivation to replace the Sharkey balloon with the Kirsch everting structure.

Moreover, the end result of substituting the everting prong structure for the Sharkey balloon would be a non-functional device: the Sharkey catheter with everting prongs in place of a balloon. The length-wise everting prong structures would seemingly be ineffective to expand

and deploy a helically-wound end of the Sharkey passive anastomosis device. On this added basis, the outstanding rejection further fails because a rejection based on a combination of prior art items is not proper if the combination would produce an inoperative device.

**The Kirsch reference has not been shows to teach a device with opposing tissue approximating structures**

Further distinguishing certain pending claims is the feature of opposing (e.g., proximal and distal) tissue approximating structures (in addition to a balloon), for example located at “fixed locations” of a catheter body relative to a distal end and a proximal end of the catheter body. See, e.g., claims 8, 31, 34, 37, 38, 41, 42, and figure 4 of the pending application. The rejection, citing figures 1-9 of the Kirsch reference, concludes that the Kirsch reference shows opposing tines that may be extended and retracted from a catheter body wall at fixed locations:

*In Figures 1-9 Kirsch et al. teach multiple distal tissue approximating tines . . . and opposing multiple proximal tissue approximating tines . . . that all extend and retract from a catheter body wall at fixed locations along the distal end of the catheter body . . .* (Emphasis added.)

This portion of the rejection fails at least because none of figures 1-9 teach opposing tines. Figures 1 and 2 each show only one set of “everting prongs” 30; there is no set of opposing tines. All of figures 3 through show the same device or another device having only one set of “everting prongs” and no opposing tines. See the text at column 3, line 25 through column 5, line 55, describing figure 1-9.

Because the cited portion of the Kirsch reference does not in fact teach opposing tines, the rejection on the cited grounds is not supported and should be withdrawn.

**Conclusion**

In view of the present remarks, Applicants submit that the outstanding rejections have been either overcome or should otherwise be withdrawn. Reconsideration of the claims, and allowance of the pending claims, are respectfully requested.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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